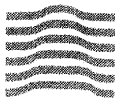
STERIS®



0160 '01 DEC 26 P2:56

December 21, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket # 00D-1543**

To Whom It May Concern:

STERIS Corporation has reviewed the recently published 21 CFR Part 11 draft guidance documents, "Guidance for Industry 21 CFR Part 11: Electronic Records; Electronic Signatures – Glossary of Terms" and "Guidance for Industry 21 CFR Part 11: Electronic Records; Electronic Signatures – Validation." STERIS is submitting comments to the guidance where it is believed to be necessary.

If you wish to discuss STERIS Corporation's comments regarding the guidance documents, please do not hesitate to contact me at (440) 392-7011.

Sincerely,

Laura M. Green
Manager, Regulatory Affairs
STERIS Corporation

00D-1543

C15

STERIS Corporation ▪ 5960 Heisley Road ▪ Mentor, OH 44060-1834 USA ▪ 440-354-2600

Section 5.8 Change Control (Configuration Management)

FDA Guidance: *Systems should be in place to control changes and evaluate the extent of revalidation that the changes would necessitate. The extent of revalidation will depend upon the change's nature, scope, and potential impact on a validated system and established operating conditions.*

Contractor or vendor upgrades or maintenance activities, especially when performed remotely (i.e., over a network), should be carefully monitored because they can introduce changes that might otherwise go unnoticed and have an adverse effect on a validated system.

You should arrange for service providers to advise you regarding the nature of such revisions so you can assess the changes and perform appropriate revalidation.

STERIS's Comments: FDA should include further guidance similar to "Deciding When to Submit a 510(k) for a Change to an Existing Device". This should include models, axioms, decision trees, discussions of risk, etc., all of which are very helpful in the manufacturer's evaluation process.

STERIS Corporation ▪ 5960 Heisley Road ▪ Mentor, OH 44060-1834 ▪ USA ▪ 440-354-2600